

## **Tribufos Reregistration Eligibility Decision Summary**

### **Closure Conference Call, September 8, 2000.**

**Purpose:** Provide an overview to stakeholders of the Agency's reregistration eligibility decision and resultant risk management decisions on tribufos through a "closure conference call."

**Background:** As a continuation of the Agency's efforts to open up the decision-making process, we are holding this "closure conference call" for interested stakeholders. The intent is to discuss the Agency's risk management decisions with them prior to final signature and release to the general public.

**Contact:** Anne Overstreet, (703) 308-8068.

**List of Invitees:** Bayer, USDA, and the National Cotton Council.

#### **I. Background**

- Tribufos is used as a cotton defoliant (prior to machine harvesting) and a bottom defoliant to reduce or prevent losses from boll rot organisms. In 1999, tribufos was applied to between 4 and 5 million acres or about 35% of planted cotton.

#### **II. Risk Management**

##### **A. Dietary (Food and Drinking Water)**

- ***Dietary food risks are low.*** Acute and chronic food risks are both less than 8.5% of the population adjusted dose for all populations and are not of concern to the Agency.
- ***Mitigation:*** None necessary
- ***Drinking water risks are low.*** The acute modeled surface drinking water concentrations of tribufos are below the DWLOC for all population sub-groups, and the chronic concentrations slightly exceed the DWLOCs for the most highly exposed sub-population (children 1 to 6 years) and are below the DWLOCs for all others. The Agency considers these modeled estimates to be conservative for several reasons, as discussed in the RED document and, therefore, the Agency is not concerned with combined dietary (food and drinking water) exposure to residues of tribufos.

- **Mitigation:** None necessary.

## **B. Occupational**

- As part of the reregistration process, the registrant has offered the following amendments to the tribufos label to address certain worker concerns.
  1. Reduce the maximum application rate to 1.5 pints per acre per year (1.125 lbs ai/A) in all states except California and Arizona, which would remain at the higher rate of 2.5 pints per acre per year (1.875 lb ai/A).
  2. Increase the restricted entry interval (REI) from 24 hours to 7 days;
  3. Distribute tribufos products in closed systems starting with the 2002 growing season.
- Even with these mitigation measures, MOEs remain below the target MOE (300 for dermal and 100 for inhalation). Risks of concern remain for workers who mix, load, and apply tribufos by aerial application (MOEs range from 49 to 150).

### ***Mitigation***

- To address the remaining concerns, the registrant has agreed to conduct a biomonitoring study. The registrant will begin by conducting a pharmacokinetics study in the monkey and, if necessary, conduct a human pharmacokinetics study for metabolite confirmation. The biomonitoring study will be submitted to the Agency by September 2003. The Agency is confident that results of the biomonitoring study will help to further refine the current risks associated with the aerial use of tribufos to a level below the Agency's concern.

### ***Benefits***

- The Agency has considered an economic impact analysis from both the USDA and the National Cotton Council and concludes that the benefits of tribufos are numerous and its loss to the cotton industry would be substantial (\$156 Million dollars for the loss incurred from both losing tribufos and decrease in yield).

## **C. Ecological**

- RQs are, in certain scenarios, exceeded for acute and chronic ecological effects resulting from tribufos use to birds, mammals, and aquatic species. The

Agency considered additional mitigation measures (buffer zones) that could be employed to address areas of risk concern. The Agency determined that buffer zones would not be necessary due to the relatively low exceedances of RQs and the impracticability of buffer zones to small farms in particular. The Agency is, therefore, not imposing buffer zones to mitigate ecological risks.

- The reduced application rate to address mixer, loader, and applicator risks will also reduce risk and exposure to ecological species. The Agency also acknowledges that tribufos is usually tank-mixed at a much lower rate which will also help to reduce exposure.

### **III. Tolerance Reassessment**

- Revoke 1 tolerance (Cottonseed hulls); not warranted based on the results of an acceptable cottonseed processing study.
- 7 tolerances remain the same (cattle meat and byproducts, cottonseed, goat meat and byproducts, and sheep meat and byproducts).

#### **The following actions cannot take place until cumulative assessments are complete:**

- Add 7 new tolerances (cotton gin byproducts; hog fat, meat and byproducts; and horse fat, meat, and byproducts). Cotton gin byproducts are added because they are now considered a raw agricultural commodity. Current Agency policy now considers hogs and horses as potential consumers of cotton gin byproducts so these tolerances will be established.
- Raise 4 tolerances (sheep fat, goat fat, milk, and cattle fat). New magnitude of residue data incorporated with cotton gin byproducts as feed additives required these tolerance to be increased.

### **IV. Wrap-Up**

- The current uses of tribufos, as stated in the RED with the above mentioned label modifications, are eligible for reregistration.
- Questions